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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/069,703	04/29/1998	GILLES H. TAPOLSKY	BSZ-092CPRCE	3665

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LAHIVE & COCKFIELD, LLP
FLOOR 30, SUITE 3000
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER	
FISHER, ABIGAIL L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/069,703	TAPOLSKY ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Request for Continued Examination and Amendments/Remarks filed on June 18 2008 is acknowledged. Claims 1-34 were/stand cancelled. Claims 35-52 were added. Claims 35-52 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 18 2008 was considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 38 claims that the backing layer is substantially occlusive to the systemic pharmaceutical. Applicants have indicated that support for this amendment can be found in examples 28 and 29 (see Interview Summary 7/15/08). Applicant has not defined substantially so it is unclear to the examiner how much of the pharmaceutical is occluded in order to meet the limitations of the instant claim. The examples of the specification indicate that the composition as a whole limits the release of the drug however these examples do not state that it is the backing that makes diffusion limited. Therefore applicant has support for the whole composition as limiting diffusion but not just the backing layer for limiting diffusion.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 38 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does

not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 39 indicates that the delivery is in a localized manner however this claim depends from claim 35 which claims the delivery is systemic. This term, localized, renders the claim indefinite because it is unclear how the administration of the same pharmaceutical is both systemic and localized.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biegajski et al. (WO 95/05416, cited in the Office action mailed on 12/20/07) as evidenced by Schiraldi et al. (US Patent No. 4713243, cited on PTO Form 1449) and Suzuki et al. (US Patent No. 4292299, cited on PTO Form 1449).

Applicant Claims

Applicant claims a transmucosal delivery device in the form of a bioerodable flexible film for the systemic delivery of a pharmaceutical, the device comprising: a bioerodable mucoadhesive layer; a bioerodable non-adhesive backing layer; and a systemic pharmaceutical incorporated into the flexible film; wherein the transmucosal delivery device is thin, flexible and orally erodes such that there is an effective residence time with minimal or no foreign body sensation.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Biegajski is directed to water-soluble pressure-sensitive mucoadhesive devices. The water-soluble pressure sensitive mucoadhesives adhere to a variety of materials such as polymers (page 5, lines 10-11). The adhesives are fully water-soluble and thus are fully soluble in secretions present in mucous-lined body cavities. Therefore, the adhesive eventually dissolves completely within the body cavity in which it is placed

(page 5, lines 20-23). One embodiment is a layered composition that includes a **polymer layer** that contains the active substance and a mucoadhesive layer that serves to affix the active-containing layer to the mucosal surface (page 8, lines 14-16). The rate of dissolution can be selected by choice of material and proportions of material in the active-containing polymer compositions. In general the dissolution rate together with the thickness determines the extent of the delivery time (page 8-9, lines 29-31 and 1-3). The delivery time can range from about 1 to about 4 hours (column 9, lines 28-30). Polymers that are listed as suitable include cellulose-type materials, natural gums, polypeptide and synthetic polymers (page 12, lines8-15). The thickness of the film is in the range of about 5 to 20 mils and is shaped to fit and conform generally to a mucosal surface (page 17, lines 19-21). One example is directed to a mucoadhesive device that has at least two layers. One is a basal layer constructed of a water soluble pressure sensitive mucoadhesive polymer and the other is an odorant containing water soluble polymer layer. The odorant containing polymer layer is made of hydroxypropyl cellulose. The adhesive polymers are those described above (page 20). It is taught in the device configurations that different substances can be contained in each layer such that they are released sequentially. The layers can also have the same dissolution rate (page 27, #2). It is taught that loss of the desired release pattern can result, therefore to minimize loss from the margins a peripheral adhesive can be provided wherein the water soluble pressure sensitive adhesive layer extend beyond the edges of the mucoadhesive layer form in a seal to prevent escape of the substance from the edges of the mucoadhesive layer (page 30, part d). This overlying layer can be impermeable

to the release substance so that the overlain layer is occluded until the overlying layer has dissolved or dispersed (page 7, lines 7-12). In one embodiment, the location of the device helps to localize the medication nearer to the site of soreness for sore throat pain (pages 9-10, lines 31 and 1-2).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Biegajski et al. do not teach that the device can be utilized to delivery the active ingredients in a systemic fashion. Biegajski et al. do not exemplify a delivery time of about 30 minutes. Biegajski et al. do not teach that the mucoadhesive layer is comprises of hydroxyethyl cellulose and hydroxypropyl cellulose. Biegajski et al. do not teach that the mucoadhesive layer comprises polyacrylic acid and sodium carboxymethyl cellulose. Biegajski et al. do not teach that the mucoadhesive layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid and sodium carboxymethyl cellulose and that the backing layer comprises hydroxyethyl cellulose and hydroxypropyl cellulose. However, these deficiencies are cured by Suzuki et al.

Suzuki et al. is directed to a preparation composed of an adhesive layer comprising polymer which have adhesiveness to a wet mucous surface and a nonadhesive layer which has no adhesiveness (abstract). Polymers that can be utilized for the adhesive layer are polyacrylic acid and salts, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, carboxymethyl cellulose or their salts. These polymers can be utilized singly or in the form a mixture (column 2, lines 44-66). The nonadhesive layer is made from water soluble or water disintegrable ingredients (column 3, lines 12-13). The active ingredients that can be utilized include

analgesics such as acetaminophen or aspirin, anti-inflammatory agents, among others (column 5, lines 12-38).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Biegajski et al. and Suzuki et al. and utilize an analgesic in the device of Biegajski et al. One of ordinary skill in the art would have been motivated to add an analgesic to a device utilized to sore throat pain in order to further aid in relief the pain associated with a sore throat. Further more, the selection of a specify drug is considered prima facie obvious depending on the desired condition/symptoms to be treated.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Biegajski et al. and Suzuki et al. and utilize polymers such as polyacrylic acid, hydroxyethyl cellulose, hydroxypropyl cellulose and sodium carboxymethyl cellulose as the adhesive layer of Biegajski et al. One of ordinary skill in the art would have been motivated to utilize these polymers as Biegajski et al. indicate that cellulose-type polymers can be utilized in the adhesive layer and Suzuki et al. indicate that these polymers are utilized in a similar type device as adhesive layer polymers. It would have been obvious to one of ordinary skill in the art to vary the types of polymer utilized in order to affect the dissolution rate of the layer as taught by Biegajski et al.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Biegajski et al. and Suzuki et al. and utilize both hydroxyethyl cellulose and hydroxypropyl cellulose as the polymer layer in invention of Biegajski et al. One of

ordinary skill in the art would have been motivated to utilize these polymers as Biegajski et al. exemplify hydroxypropyl cellulose can be utilized in the polymer layer and both are taught as functional equivalents by Biegajski et al. and Suzuki et al. Furthermore, Biegajski et al. indicate that the layers can have the same dissolution. The easiest way to achieve the same dissolution rate for the layers would to be to utilize the same material for both layers.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Biegajski et al. and Suzuki et al. and vary the amount and type of polymers as well as the thickness of the layers to vary the delivery time of the active component. One of ordinary skill in the art would have been motivated to vary these components as Biegajski et al. teach that these are the factors that determine the delivery time for the drug. Therefore, one of ordinary skill in the art would have been motivated to vary these components to either increase or prolong the release depending on what was desired for a particular active ingredient.

Regarding instant claim 36, Biegajski et al. teach that the thickness is in the rage of about 5 to 20 mils. As evidenced by Schiraldi et al., 4 mils is approximately equal to 0.1 mm (column 4, lines 61-62). Therefore 5 to 20 mils is approximately 0.125 to 0.5 mm.

Regarding the functional limitation of minimal or no foreign body sensation, Biegajski et al. indicate that the device is shaped to fit and conform generally to a mucosal surface. Schiraldi et al. indicate that films of a thickness 0.025 to 0.25 mm are so thin that when placed in the mouth they are unobtrusive and hardly noticeable by

most patients. Therefore, since the thickness of the device of Biegajski et al. is the same as Schiraldi et al. there is a reasonable expectation that it also would be hardly noticeable to most patients.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biegajski et al. as evidenced by Schiraldi et al. in view of Suzuki et al. and in further view of Khanna et al. (US Patent No. 4857336).

Applicant Claims

Applicant claims that the device further comprises a hydrophilc salt. A specific species claimed is sodium benzoate.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Biegajski et al., Schiraldi et al, and Suzuki et al. are set forth above. Specifically, Biegajski et al. teach water-soluble pressure-sensitive mucoadhesive devices.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Biegajski et al. do not teach that a hydrophilc salt such as sodium benzoate can be incorporated. However, this deficiency is cured by Khanna et al.

Khanna et al. teach a therapeutic system for peroral administration. It is taught sparingly soluble drugs do not create enough osmotic pressure to effectively release from the polymer core. To solve this problems water-soluble auxiliary such as salts or sugars are utilized for producing an osmotic pressure to help expel the drug (column 1, lines 29-55). Water soluble compounds utilized for inducing osmosis are inorganic salts and salts of organic acids such as sodium benzoate (column 6, lines 14-20).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Biegajski et al., Suzuki et al., and Khanna et al. and utilize sodium benzoate in the device of Biegajski et al. One of ordinary skill in the art would have been motivated to utilize sodium benzoate when utilizing sparing soluble active agents as they are taught by Khanna et al. as not able to produce enough osmotic pressure to release from a layered device and this problem can be remedied by the incorporation of osmotic inducing compounds such as sodium benzoate.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Although the previous rejection has been withdrawn the examiner would like to address Applicants arguments regarding Biegajski et al. as that reference has been maintained in the current Office action.

Applicants argue that Biegajski et al. does not disclose nor exemplify the transmucosal delivery of a systemic pharmaceutical. First, the selection of a specify drug is considered prima facie obvious depending on the desired condition/symptoms to be treated. Second, the administration of a systemic drug would have been obvious in view of the secondary reference to Suzuki et al. Biegajski et al. teach the administration of drugs to treat sore throat pain. Suzuki et al. teach the administration of analgesic such as aspirin or acetaminophen in a similar device. Therefore, it would have been obvious to one of ordinary skill in the art to add the analgesic systemic compounds such as aspirin or acetaminophen to further aid in the treatment of the pain associated with a sore throat.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-46 and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5800832 in view of Biegajski et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a transmucosal delivery device in the form of a bioerodable flexible film for the systemic delivery of a pharmaceutical, the device comprising: a bioerodable mucoadhesive layer; a bioerodable non-adhesive backing layer; and a systemic pharmaceutical incorporated into the flexible film; wherein the transmucosal delivery device is thin, flexible and orally erodes such that there is an effective residence time with minimal or no foreign body sensation.

Patent '832 claims a bioerodable, water-soluble pharmaceutical carrier device comprising a layered film having a first water-soluble adhesive layer and a second water soluble non-adhesive backing layer and a pharmaceutical or combination of pharmaceuticals incorporated within said first or second layers. The first water-soluble adhesive layer comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose. Said second water-soluble non-adhesive backing layer comprises hydroxyethyl cellulose.

Patent '832 does not claim a particular residence time or thickness. However, these deficiencies are cured by Biegajski et al.

Biegajski et al. is directed to water-soluble pressure-sensitive mucoadhesive devices. The rate of dissolution can be selected by choice of material and proportions of material in the active-containing polymer compositions. In general the dissolution rate together with the thickness determines the extent of the delivery time (page 8-9, lines 29-31 and 1-3). The thickness of the film is in the range of about 5 to 20 mils and is shaped to fit and conform generally to a mucosal surface (page 13, lines 11-12).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '832 and Biegajski et al. and vary the type and amount of polymers utilized as well as the thickness of the device. One of ordinary skill in the art would have been motivated to vary these components in order to optimize the dissolution time of the layers of the device as taught by Biegajski et al.

Therefore, the scopes of the Patent '832 and the instant application overlap and thus they are obvious variants of one another.

Claims 47 and 49-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5800832 in view of Biegajski et al. and Suzuki et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The claims of the instant invention are set forth above.

The claims of Patent '832 are set forth above.

Patent '832 does not claim that the mucoadhesive layer is comprises of hydroxyethyl cellulose and hydroxypropyl cellulose. Patent '832 does not claim that the mucoadhesive layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid and sodium carboxymethyl cellulose and that the backing layer comprises hydroxyethyl cellulose and hydroxypropyl cellulose. However, these deficiencies are cured by Suzuki et al.

Suzuki et al. is directed to a preparation composed of an adhesive layer comprising polymer which have adhesiveness to a wet mucous surface and a nonadhesive layer which has no adhesiveness (abstract). Polymers that can be utilized for the adhesive layer are polyacrylic acid and salts, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, carboxymethyl cellulose or their salts. These polymers can be utilized singly or in the form a mixture (column 2, lines 44-66). The nonadhesive layer is made from water soluble or water disintegrable ingredients such as those above (column 3, lines 12-13).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '832, Biegajski et al. and Suzuki et al. and utilize polymer such as polyacrylic acid, hydroxyethyl cellulose, hydroxypropyl cellulose and sodium carboxymethyl cellulose as the adhesive layer of Patent '832. One of ordinary skill in the art would have been motivated to utilize these polymers as Patent '832 claims hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose can be utilized in the adhesive layer and Suzuki et al. indicate that these polymers are utilized in a similar type device as adhesive layer polymers. It would have been obvious to one

of ordinary skill in the art to vary the types of polymer utilized in order to affect the dissolution rate of the layer as taught by Biegajski et al.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '832, Biegajski et al., and Suzuki et al. and utilize both hydroxyethyl cellulose and hydroxypropyl cellulose as the polymer layer in invention of Patent '832. One of ordinary skill in the art would have been motivated to utilize these polymers as Patent "832 claims hydroxyethyl cellulose can be utilized in the backing layer and both are taught as functional equivalents by Suzuki et al.

Therefore, the scopes of the Patent '832 and the instant application overlap and thus they are obvious variants of one another.

Claims 51-52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5800832 in view of Biegajski et al. and Khanna et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The claims of the instant invention are set forth above.

The claims of Patent '832 are set forth above.

Patent '832 does not claim that the device further comprises sodium benzoate. However, this deficiency is cured by Khanna et al.

Khanna et al. teach a therapeutic system for peroral administration. It is taught sparingly soluble drugs do not create enough osmotic pressure to effectively release from the polymer core. To solve this problems water-soluble auxiliary such as salts or

sugars are utilized for producing an osmotic pressure to help expel the drug (column 1, lines 29-55). Water soluble compounds utilized for inducing osmosis are inorganic salts and salts of organic acids such as sodium benzoate (column 6, lines 14-20).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '892, Biegajski et al. and Khanna et al. and utilize sodium benzoate in the device of Patent '892. One of ordinary skill in the art would have been motivated to utilize sodium benzoate when utilizing sparing soluble active agents as they are taught by Khanna et al. as not being able to produce enough osmotic pressure to release from a layered device and this problem can be remedied by the incorporation of osmotic inducing compounds such as sodium benzoate.

Therefore, the scopes of Patent '832 and the instant application overlap and thus they are obvious variants of one another.

Claims 35-46 and 48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-27 of U.S. Patent No. 6159498 in view of Biegajski et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The claims of the invention are set forth above.

Patent '498 claims a biodegradable water soluble pharmaceutical carrier device comprising a layered flexible film having a first water soluble adhesive layer to be placed in contact with the mucosal surface and a second water-soluble non-adhesive

backing layer and a pharmaceutical or combination of pharmaceuticals incorporated within said first or second layer. The first layer comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose. The second layer comprises hydroxyethyl cellulose.

Patent '498 does not claim a residence time or thickness. However, these deficiencies are cured by Biegajski et al.

The teachings of Biegajski et al. are set forth above.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '498 and Biegajski et al. and vary the type and amount of polymers utilized as well as the thickness of the device. One of ordinary skill in the art would have been motivated to vary these components in order to optimize the dissolution time of the layers of the device as taught by Biegajski et al.

Therefore, the scopes of the Patent '498 and the instant application overlap and thus they are obvious variants of one another.

Claims 47 and 49-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-27 of U.S. Patent No. 6159498 in view of Biegajski et al. and Suzuki et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The claims of the instant invention are set forth above.

The claims of Patent '498 are set forth above.

Patent '498 does not claim that the mucoadhesive layer is comprises of hydroxyethyl cellulose and hydroxypropyl cellulose. Patent '498 does not claim that the mucoadhesive layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid and sodium carboxymethyl cellulose and that the backing layer comprises hydroxyethyl cellulose and hydroxypropyl cellulose.

Patent '498 does not claim that the mucoadhesive layer is comprises of hydroxyethyl cellulose and hydroxypropyl cellulose. Patent '498 does not claim that the mucoadhesive layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid and sodium carboxymethyl cellulose and that the backing layer comprises hydroxyethyl cellulose and hydroxypropyl cellulose. However, these deficiencies are cured by Suzuki et al.

The teachings of Suzuki et al. are set forth above.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '498, Biegajski et al. and Suzuki et al. and utilize polymer such as polyacrylic acid, hydroxyethyl cellulose, hydroxypropyl cellulose and sodium carboxymethyl cellulose as the adhesive layer of Patent '498. One of ordinary skill in the art would have been motivated to utilize these polymers as Patent '498 claims hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose can be utilized in the adhesive layer and Suzuki et al. indicate that these polymers are utilized in a similar type device as adhesive layer polymers. It would have been obvious to one of ordinary skill in the art to vary the types of polymer utilized in order to affect the dissolution rate of the layer as taught by Biegajski et al.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '498, Biegajski et al. and Suzuki et al. and utilize both hydroxyethyl cellulose and hydroxypropyl cellulose as the polymer layer in invention of Patent '498. One of ordinary skill in the art would have been motivated to utilize these polymers as Patent '498 claims hydroxyethyl cellulose can be utilized in the backing layer and both are taught as functional equivalents by Suzuki et al.

Therefore, the scopes of the Patent '498 and the instant application overlap and thus they are obvious variants of one another.

Claims 51-52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-27 of U.S. Patent No. 6159498 in view of Biegajski et al. and Khanna et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The claims of the instant invention are set forth above.

The claims of Patent '498 are set forth above.

Patent '498 does not claim that the device further comprises sodium benzoate. However, this deficiency is cured by Khanna et al.

The teachings of Khanna et al. are set forth above.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '498, Biegajski et al. and Khanna et al. and utilize sodium benzoate in the device of Patent '498. One of ordinary skill in the art would have been motivated

to utilize sodium benzoate when utilizing sparing soluble active agents as they are taught by Khanna et al. as not able to produce enough osmotic pressure to release from a layered device and this problem can be remedied by the incorporation of osmotic inducing compounds such as sodium benzoate.

Therefore, the scopes of Patent '498 and the instant application overlap and thus they are obvious variants of one another.

Claims 35-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 11-12, 14, 17, 27-28, 32-36, 38-42 and 45 of copending Application No. 11817915. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The claims of the invention are set forth above.

Copending '915 claims a method for enhancing direct transmucosal delivery of a fentanyl or fentanyl derivative to a subject comprising administering a bioerodable drug delivery device to an oral mucosal surface comprising a fentanyl derivative disposed in a mucoadhesive polymeric diffusion environment and a barrier environment disposed to the polymer environment. Systemic delivery is claimed. A backing layer disposed adjacent to the mucoadhesive layer is claimed. Sodium benzoate is claimed. A thickness of about 0.25 mm is claimed.

Copending '915 does not claim specific polymers of the mucoadhesive or backing layer. However, this deficiency is cured by Suzuki et al.

The teachings of Suzuki et al. are set forth above.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Copending '915 and Suzuki et al. and utilize polymer such as polyacrylic acid, hydroxyethyl cellulose, hydroxypropyl cellulose and sodium carboxymethyl cellulose as the adhesive layer of Copending '915. One of ordinary skill in the art would have been motivated to utilize these polymers as Suzuki indicate hydroxypropyl cellulose, hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose can be utilized in the adhesive layer of a similar device.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Copending '915 Suzuki et al. and utilize both hydroxyethyl cellulose and hydroxypropyl cellulose as the polymer layer in invention of Biegajski et al. One of ordinary skill in the art would have been motivated to utilize these polymers as Suzuki et al. teach that they can be utilized as a backing layer of a similar device.

Therefore, the scopes of the Copending '915 and the instant application overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616